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(c) inserting an at least partially contracted stent into the tube, the stent having an inner surface and an outer surface;

(d) radially expanding the stent in the tube or allowing the stent to radially expand in the tube;

(e) evaporating at least part of the solvent; and

(f) polymerizing the elastomeric composition.

#### REMARKS

The applicant thanks the Office for careful consideration given the application in the communication. Reconsideration of claims 9-14, and consideration of new claim 15-19 are respectfully requested. Claims 9-14 have been amended to address the foregoing rejections.

Support for adding "coating the inner surface of a tube with a lifting medium" in claim 9, can be found in the applicant's application, inter alia on page 4, lines 1-16.

Support for adding "preparing an elastomeric composition dissolved in a solvent" in claim 9 can be found in the applicant's application, inter alia on page 4, lines 19-20; page 5, lines 6-10; page 5, line 34 thru page 6, line 2; and page 6 lines 25-28.

In response to the various rejections against claims 9-14 under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite, applicant submits that the

rejections have been obviated in view of amendments made to the claims and respectfully asks that examiner to reconsider and withdraw the rejections. Claims 9-14 have been rewritten to define the invention more particularly and over the cited documents. Support and clarity can be found in the amended claim language.

In response to the information disclosure statement filed November 29, 1994, the copies of documents listed were not included because under 37 C.F.R. § 1.98(d), additional copies are not necessary, as this application, is a divisional application and the copies have been previously submitted to the PTO in a prior patent application, Serial No. 08/173,542, filed on December 22, 1993, which is relied upon for an earlier filing date under 35 U.S.C. § 120. A Supplemental Information Disclosure Statement reflecting this information is included with this Amendment.

Claims 9-14 stand rejected under 35 U.S.C. § 103, as being allegedly unpatentable. The various rejections of claims 9-14 under 35 U.S.C. § 103 are respectfully traversed.

A discussion of the present invention follows, but preliminarily, the applicant comments about the documents

Stoy, individually and in various combination in view of MacGregor, Montgomery, Meyers, Stobie or Anderson. These documents do not establish a prima facie basis for obviousness.

Stoy does not suggest a need for or a method for applying a covering layer to a stent. Stoy is directed to guidewires and their methods of production, specifically an elongated non-hydrogel core element forming an inner part of the device, and an integral outside tubular layer of elastomeric hydrogel (abstract). The applicant's invention relates to stents with coverings and methods for applying the layer on the stent. Stoy does not disclose a method for applying a covering layer to a stent where a stent may be radially contracted and inserted into a tube. Stoy discloses expansion of the hydrogel layer and in increasing size of its lumen (column 6, line 23-24). The outer hydrogel sleeve is made from a gradient of chemical composition and swelling such that use substantially more hydrophobic on its inner surface contacting said core element than it is on its outside surface (column 5, line 22-25). The applicant's invention does not involve hydrogel and solves a different

problem than Stoy. Also, Stoy lacks a step of radially contracting a stent in order to insert it into a tube.

The Stoy document teaches away from the present invention. In fact, Stoy teaches applying the hydrogel sleeve on the core element or at least a portion of it, which has O.D. larger than I.D. of the sleeve. According to Stoy, this can be readily achieved by applying the sleeve in state of higher than equilibrium swelling (column 6, lines 17-21). On the contrary, applicant's invention involves radially contracting the stent and inserting at least a portion of the contracted stent into a tube.

MacGregor discloses that stents may be deployed in an integral tubular configuration (column 5, lines 61-62), that the stent may be compressed circumferentially (column 5, lines 65-66), that adhesives, which may be biocompatible and hemocompatible, may also be used for bonding purposes (column 5, lines 35-37) and bonding of an appropriate coating directly to the exterior surface of the stent (column 5, lines 54-56). The applicant's invention relates to a stent with a covering layer of elastic material and methods for applying the layer on the stent. There is no teaching in MacGregor with reference to the applicant's

steps of radially contracting the stent, coating the inner surface of a tube with a lifting medium, inserting at least a portion of the contracted stent into the tube, radially expanding the stent, coating the tube and stent with the elastomeric polymerisable composition dissolved in solvent, evaporating the solvent and polymerizing the elastomeric composition dissolved in a solvent and forming at least a portion of a layer on the stent in the tube and removing the stent out of the tube.

Montgomery teaches an article which includes two surfaces in sliding contact (column 2, lines 67-68), a multilayer lubricant system (column 3, lines 3-4) and a method for lubricating an article (abstract). There is no teaching in Montgomery with reference to the applicant's steps of radially contracting the stent, coating the inner surface of a tube with a lifting medium, inserting at least a portion of the contracted stent into the tube, radially expanding the stent, coating the tube and stent with the elastomeric polymerisable composition dissolved in solvent, evaporating the solvent and polymerizing the elastomeric composition dissolved in a solvent and forming at least a

portion of a layer on the stent in the tube and removing the stent out of the tube.

Meyers discloses a flexible pipe connector made of an inert polymer which can be connected to a hard plastic pipe by virtue of a series of undercuts formed on the plastic pipe connector to receive liquified hard plastic when a solvent weld glue is applied to the hard plastic pipe (column 1, lines 6-12). There is no teaching in Meyers with reference to the applicant's steps of radially contracting the stent, coating the inner surface of a tube with a lifting medium, inserting at least a portion of the contracted stent into the tube, radially expanding the stent, coating the tube and stent with the elastomeric polymerisable composition dissolved in solvent, evaporating the solvent and polymerizing the elastomeric composition dissolved in a solvent and forming at least a portion of a layer on the stent in the tube and removing the stent out of the tube.

Stobie teaches adhesively bonding an at least partially hollow first member to a second member received interiorly of the first. Adhesive is applied to the second member and allowed to attain a substantially non-flowable condition

(abstract). Stobie also describes an adhesive dispenser  
(abstract). There is no teaching or suggesting in Stobie  
with reference to the applicant's steps of radially  
contracting the stent, coating the inner surface of a tube  
with a lifting medium, inserting at least a portion of the  
contracted stent into the tube, radially expanding the  
stent, coating the tube and stent with the elastomeric  
polymerisable composition dissolved in solvent, evaporating  
the solvent and polymerizing the elastomeric composition  
dissolved in a solvent and forming at least a portion of a  
layer on the stent in the tube and removing the stent out of  
the tube.

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Anderson discloses catheters for long term implantation  
having polymer surfaces in face-to-face contact which are  
provided with a thin film coating of a glow discharged  
plasma polymerized fluorocarbon to prevent adhesion of the  
contacting surface (abstract). There is no teaching in  
Anderson with reference to the applicant's steps of radially  
contracting the stent, coating the inner surface of a tube  
with a lifting medium, inserting at least a portion of the  
contracted stent into the tube, radially expanding the  
stent, coating the tube and stent with the elastomeric

polymerisable composition dissolved in solvent, evaporating the solvent and polymerizing the elastomeric composition dissolved in a solvent and forming at least a portion of a layer on the stent in the tube and removing the stent out of the tube.

In rejecting claims under 35 U.S.C. § 103 the examiner bears the burden of presenting a prima facie case of obviousness. The prior art fails to establish a basis for obviousness.

The examiner fails to show that the claimed subject matter in claims 9-14, as a whole, would have been obvious to a person of ordinary skill in the art to which the subject matter pertains at the time the invention was made. There are no teachings in the prior art that would lead one of ordinary skill in the art to combine the relevant teachings of the documents.

To conclude, applicant submits that claims 9-14 and new claims 15-19 define subject matter patentable over the prior art of record.

Applicant requests reconsideration and submits that claims 9-14, as amended, and new claims 15-19 are in condition for allowance.



Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the office action of March 30, 1995 in Application Serial No. 08/346,066 filed November 29, 1994 is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, postage prepaid, on August 11, 1995.



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